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## 2nd Medtronic Consultant Draws Senate's Scrutiny

## By BARRY MEIER

A Senate investigation of ties between doctors and the medical device maker <u>Medtronic</u> is putting a spotlight on another of the company's consultants.

That physician, Dr. David W. Polly Jr., urged members of a Senate panel in 2006 to continue paying for Defense Department medical research into combat-related injuries. But Dr. Polly did not disclose during his testimony that he was a Medtronic consultant and was billing the company \$6,000 for his appearance, according to documents released Tuesday. Instead, he told lawmakers that he was representing a professional medical association of orthopedic surgeons, according to the documents.

Dr. Polly, who is a medical professor at the <u>University of Minnesota</u>, subsequently received some of the Defense Department research funds, to head an animal study involving a Medtronic bone growth product called Infuse, according to the documents.

Dr. Polly is the latest academic researcher to come under scrutiny in the Senate investigation, which is being conducted by <u>Charles E. Grassley</u> of Iowa, the ranking Republican member of the Senate Finance Committee.

Senator Grassley publicly released a <u>number of documents</u>, including Dr. Polly's bills to Medtronic, as part of a continuing investigation into the company's marketing of Infuse, a bioengineered bone growth product.

Between 2003 and 2007, Dr. Polly received more than \$1.14 million in fees and expenses from Medtronic, those records show. And the extent of his financial entanglements with the company, as detailed by those records, could raise questions about the ability of academic medical centers to manage potential conflicts of interest by faculty members who are also highly paid consultants to medical product companies.

In late 2006, university officials allowed him to work on the Defense Department-financed study of Infuse. The medical school knew he was a company consultant, but under the school's rules Dr. Polly had to acknowledge only that he received more than \$10,000 annually. Medtronic paid him about \$350,000 that year alone in expenses and fees, the records show.

In an interview and subsequent e-mail messages this week, Dr. Polly said that he had done nothing wrong in connection with his 2006 appearance at the hearing, which was conducted by the Defense Subcommittee of the Senate Appropriations Committee. A transcript of that hearing shows that he identified himself at the hearing as a representative of a professional medical group, the American Academy of Orthopedic Surgeons. He did not note his ties to Medtronic, according to the transcript.

The documents released Tuesday also indicate that for his appearance at the hearing, Dr. Polly billed Medtronic \$6,000.

Dr. Polly said this week that he could not address specific questions about charges to Medtronic because his billing records were not immediately available. "If I billed Medtronic for services that were inappropriate I would be happy to refund that money," he said in the interview. "My relationship with the company has always been on the up-and-up."

Dr. Polly's study, which the Defense Department paid over \$466,000 to support, involved laboratory animals and was intended to show whether the use of various antibiotics in combination with Infuse could speed the healing of badly fractured shin bones that were also deeply infected.

Such trauma injuries are common in soldiers wounded in Iraq by roadside bombs and other explosive devices.

Until 2003, Dr. Polly was the head of the orthopedics department at Walter Reed Army Medical Center in Washington.

He is the second former Walter Reed doctor to come under scrutiny by Senator Grassley. The other, <u>Dr. Timothy R. Kuklo</u>, published a study of Infuse's use on Walter Reed patients that a British medical journal retracted in March after an Army investigation concluded that he had falsified its results.

Dr. Polly is an author on an influential Medtronic-sponsored study that found that the use of Infuse, a bioengineered protein that stimulates bone growth, was cost-effective in spinal fusions when compared with using bone grafts, the traditional material.

While he was still in the military, Medtronic paid his traveling expenses for medical meetings in this country and abroad.

The general counsel of the University of Minnesota, Mark Rotenberg, said that the medical school had allowed Dr. Polly to work on the Defense Department study despite his ties to Medtronic because the study involved laboratory rats, rather than people, and because Dr. Polly had said that it was not of economic significance to the company. The medical school instructed him not to disclose any data from the study to Medtronic before its public release.

Asked about Dr. Polly's testimony, Medtronic said it believed that he should have disclosed that the company had paid him for his preparation for the 2006 hearing and his travel. Late Tuesday, Medtronic said it plans to conduct an internal inquiry of Dr. Polly's activities and would soon announce new policies regarding consultants that covered disclosure-related issues.

A lawyer for Dr. Polly, John Lundquist, said the physician will review any concerns about how he tracked and billed for consulting activities. Duff Wilson contributed reporting.